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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,135	12/01/2003	Robert F. Rosenbluth	MCRVT-029G	3524

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EXAMINER	
WOO, JULIAN W	
ART UNIT	**PAPER NUMBER**
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

NT

Office Action Summary	Application No.	Applicant(s)	
	10/726,135	ROSENBLUTH ET AL.	
	Examiner	Art Unit	
	Julian Woo	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *79-117* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *79-117* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/1/03,10/26/04,12/8/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 79-96, 100-108, 112, and 114-116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wholey et al. (2002/0169497) in view of Greene, Jr. et al. (6,238,403). Wholey et al. disclose, at least in figures 7 and 24 and in paragraphs [0045] and [0050] to [0052], the invention substantially as claimed. Wholey et al. disclose a method for preventing leakage into a perigraft space (14) between an endovascular graft (e.g., 28) and an adjacent portion of an aneurysmic blood vessel wall, where a device comprising a solid member (36) having expansile polymeric material (e.g., gel, organic elastomers, and polymeric foams) disposed thereon is provided, a flexible cannula (32) is inserted into a perigraft space between the endovascular graft and the blood vessel wall;the device is introduced through the

cannula, through a portion of the graft, and into the perigraft space; and the graft is implanted prior to inserting the cannula into the perigraft space. However, Wholey et al. do not disclose that the expansile polymeric material is substantially in a non-expanded state when it is introduced into the perigraft space through the cannula and allowed to expand to an expanded state in the perigraft space. Greene, Jr. et al. teach, at least in figures 1-7 and in col. 3, line 50 to col. 4, line 41; a method of treating an aneurysm, where a device (10) comprising an expansile polymeric material (e.g., hydrogel foam or PVA foam) is introduced through a cannula in a non-expanded state allowed to expand to an expanded state in an aneurysmic space. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the device as taught by Greene, Jr. et al. in the method of Wholey et al. Such a device, at deployment, would allow excellent locational control with a low risk of tissue damage or migration, and it would allow effective embolization of an entire aneurysmic site. Wholey et al. also do not disclose that the total volume of non-expanded expansile polymeric material is predetermined before its expansion in the perigraft space. Green, Jr. et al. teach, in col. 8, lines 37-43, determining a volume of an aneurysm in order to predetemine a volume of non-expanded expansile polymeric material before its expansion in the aneurysm. Thus, it would have been obvious to one having ordinary skill in the art to predetermine the total volume of non-expanded expansile polymeric material to be deployed in the perigraft space. Such a predetermination would allow the selection of an appropriate size for the device, so that it would expand and fill the perigraft space that has been sized. Wholey et al. do not disclose that the expansile

polymeric material is radiopaque or radiopaque by the incorporation of radiopaque monomers. Greene, Jr. et al. teach, in col. 6, lines 14-25, an expansile polymeric material that is radiopaque or radiopaque by the incorporation of radiopaque monomers. Thus, it would have been obvious to modify the expansile polymeric material of the device of Wholey et al, so that is radiopaque. Radiopacity would allow visualization of the device by conventional imaging techniques. Wholey et al. do not disclose that the polymeric material expands to its expanded state in an environment having a pH of about 7.4 or as the pH of the environment increases. Nevertheless, it would have been obvious to one having ordinary skill to apply a material so that it expands at a pH of about 7.4 or as the pH of the environment increases, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. Wholey et al. do not disclose that the device is initially attached to a delivery member by way of a detachable connection. Greene, Jr. et al. teach, in col. 7, lines 19-34; a device that is initially attached to a delivery member (30) by way of detachable connection (24). It would have been obvious to one having ordinary skill to modify the device of Wholey et al., so that it has the characteristics as taught by the device (10) of Greene, Jr. et al. Such a device and a delivery member would ease deployment of the device into the perigraft space and allow rapid separation of the device from the delivery member and the cannula. Wholey et al. also do not disclose that the solid member is an elongate, filamentous, or wire member; that the polymeric material is in the form of pellets spaced apart by coil spacers comprising the solid member, and that the solid member is formed of platinum, platinum and tungsten, polymeric material, or PVA.

Greene, Jr. et al. teach, in col. 5, lines 12-46, a solid member and spacers (14, 16) and polymeric material (12) as claimed above. It would have obvious to one having ordinary skill in the art to modify the solid member and polymeric material of the device of Wholey et al. to the characteristics as claimed and as taught by Greene, Jr. et al. Such a solid member and a porous, hydrophilic, polymeric material would produce a highly flexible, biocompatible, and visible device that can easily be deployed through a cannula to an aneurysmic site, where the device would effectively embolize. Wholey et al. and/or Greene, Jr. et al. do not disclose/teach the pore size or porosity of the polymeric material as claimed. Nevertheless, it has been held that discovering an optimum value of a result effective variable (pore size or porosity) involves only routine skill in the art. Wholey et al. and/or Greene, Jr. et al. do not disclose that the cannula comprises a plastic tube. Nevertheless, it has been held to be within the general skill of a worker in the art to select a known material on the basis for its suitability for its intended use as a matter of design choice. Wholey et al. and/or Greene, Jr. et al. do not disclose performing the method after detection of an endoleak. Nevertheless, it would have been obvious to one having ordinary skill in the art to perform the method after detection of the endoleak in order to pinpoint the leak, embolize the located site, and prevent future leakage.

3. Claims 79, 97-99, 107, 110, and 117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smalling (6,730,119) in view of in view of Greene, Jr. et al. (6,238,403). Smalling discloses, at least in figures 1A and 6A and in col. 14, line 40 to col. 15, line 27; the invention substantially as claimed. Smalling discloses a method for

preventing leakage into a perigraft space (305) between an endovascular graft (1100) and an adjacent portion of an aneurysmic blood vessel wall, where a device comprising a solid member (310) having expansile polymeric material (e.g., coils, foam, and gel) disposed thereon is provided, a cannula (410) is inserted into a perigraft space between the endovascular graft and the blood vessel wall; the device is introduced through the cannula, through a catheter or microcatheter (400), and into the perigraft space; where the cannula is also advanced through a hollow needle (192) in tissue of a patient's body. However, Smalley does not disclose that the expansile polymeric material is substantially in a non-expanded state when it is introduced into the perigraft space through the cannula and allowed to expand to an expanded state in the perigraft space. Greene, Jr. et al. teach, at least in figures 1-7 and in col. 3, line 50 to col. 4, line 41; a method of treating an aneurysm, where a device (10) comprising an expansile polymeric material (e.g., hydrogel foam or PVA foam) is introduced through a cannula in a non-expanded state allowed to expand to an expanded state in an aneurysmic space. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the device as taught by Greene, Jr. et al. in Smalley's method. Such a device, at deployment, would allow excellent locational control with a low risk of tissue damage or migration, and it would allow effective embolization of an entire aneurysmic site. Smalley also does not disclose that the microcatheter has a lumen of .005-050 inch in diameter. Nevertheless, it would have been a matter of obvious design choice to one having ordinary skill in the art at the time the invention was made to size the lumen as claimed, since such a modification would have involved

a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

4. Claims 109, 111, and 113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wholey et al. in view of Greene, Jr. et al. as applied to claims 79 and 107 above, and further in view of Goupil et al. (6,676,971). Wholey et al. in view of Greene, Jr. et al. disclose the invention substantially as claimed, but do not disclose advancing the distal end of the cannula through tissue of a patient's body and through the wall of the blood vessel adjacent to the graft and into the perigraft space, where the cannula is rigid or comprises a metal tube. Goupil et al. teach, in col. 18, lines 41-63, accessing a perigraft space with a cannula (a catheter or a syringe) for delivery of an embolic device, where the distal end of the cannula may be advanced through a patient's body (e.g., a patient's back) and through the wall of the blood vessel adjacent to the graft and into the perigraft space. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Wholey et al. in view of Greene, Jr. et al. in order advance the distal end of the cannula through tissue of a patient's body and through the wall of the blood vessel adjacent to the graft and into the perigraft space. Such a practice would allow access to a perigraft space that would be difficult to reach endovascularly. It would also be obvious to apply a substantially rigid cannula or a cannula formed of a metal tube in the method, since such a cannula would allow penetration of tissue for access to the perigraft space. That is, it is held to be within the general skill of a worker in the art to select a known material

(e.g., a rigid or metal material) on the basis of its suitability for the intended use as a matter of obvious design choice.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chin et al. (5,928,260), McCrory (5,951,599), and Brown et al. (6,093,199) teach methods of treating aneurysmic blood vessels.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Julian W. Woo
Primary Examiner

December 22, 2006